Remarks:

Claims 1-22 are pending in the application.

Claims 1-22 are rejected; claim 19 is also objected to.

Objection to claim 19

Claim 19 is objected to because the word "making" in the phrase "taste making" appears to be a typographical error.

Claim 19 has been amended to correct the error by deleting the word "making" and replacing it with the word "masking" and a hyphen, so that the original phrase "taste marking" now reads "taste-masking". Support for "taste-masking" may be found in paragraph [0054] of the present printed application publication No. U.S. 2004/0121015.

Reconsideration and withdrawal of the objection is therefore respectfully requested.

Claim Rejection-35 USC 112

Claim 8 is rejected under 35 U.S.C. 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants believe to be their invention. The basis given for the rejection is that claim 8 improperly recites a Markush expression in the alternative, i.e. by use of the word "or" instead of "and".

Claim 8 has been appropriately amended, by replacing the objected-to "or" with "and".

Reconsideration and withdrawal of the rejection is therefore respectfully requested.

Claim Rejections-35 USC 103

(1). Claims 1-7 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour US 6,004,582.

The basis given for the rejection is as follows:

Faour teaches a process for preparing an osmotic dosage form comprising an active core (5), a semipermeable membrane (4), a water-soluble polymer coat (3), and an immediate release active agent-containing external coat (2) (column 4, lines 63 through column 6, lines 1-13; and Fig. 2). The claimed active agents can be found in columns 13-15). Faour further teaches the dosage form is suitable to deliver one or more active agents to an environment of use in a controlled manner (abstract; column 1, lines 4-22; and column 5, lines 1-3). Semipermeable membrane includes cellulose acetate

and polyethylene glycol (column 4, lines 24-34; column 9, lines 1-27; and examples). Faour further teaches a taste masked finish coating (8) (column 17, lines 58-64; and examples).

Faour does not explicitly teach the claimed properties, such as the time to release 50% of the active agent into the use environment is at least 0.5 fold, but less than 2.0 fold the time required for the composition to release 50% of said active agent into a control use environment comprising less than about 0.1% dietary fat. Faour further does not teach the percent amount of dietary fat in the use environment.

However; it is noted Faour teaches the use of the claimed polymeric coating, e.g., cellulose acetate, in a similar osmotic dosage form for a controlled release of active agent to the same use environment, such as GI tract. Accordingly, the use of identical structures necessitates similar properties desired by the applicant. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable.

Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

When the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

Thus, one of ordinary skill in the art would have been motivated to, by routine experimentation modify the controlled release osmotic dosage form of Faour to obtain the claimed invention, because **Faour teaches using similar polymeric coating for the same purpose, namely to deliver active agents to the use environment in a controlled manner.** (Emphasis added)

As stated by the Office, Faour does not explicitly teach the claimed properties, such as the time to release 50% of the active agent into the use environment is at least 0.5 fold, but less than 2.0 fold the time required for the composition to release 50% of said active agent into a control use environment comprising less than about 0.1% dietary fat. Faour further does not teach the percent amount of dietary fat in the use environment.

However, Faour's compositions having a semipermeable membrane that includes cellulose acetate and polyethylene glycol were deemed to be the same as the compositions defined in the present claims, and, therefore, were found to inherently possess the claimed properties.

It is respectfully submitted that the claimed compositions are different from Faour's compositions.

The compositions described in all of the rejected claims require the presence of an **asymmetric** polymeric coating on the active-substance-containing core. Faour does not teach or suggest asymmetric polymeric coatings.

Asymmetric coatings are discussed in paragraph [0109] of the present application thusly:

[0109] Asymmetric coatings are known to the art, for example as disclosed in U.S. Pat. No. 5,612,059 to Cardinal et al. Such coatings are membranes that consist of a very thin, dense skin supported by a thicker, porous substructure layer. Delivery devices that can be made with asymmetric membranes include tablets, capsules, and beads. Such membranes can be made by a phase inversion process, as disclosed in the aforementioned patent. Advantageously, and as also disclosed therein, the porosity of the membrane can be implemented in a controlled manner such that the porosity, and hence the rate of release, can be tailored. By tailoring the rate of release, the release profile of the resulting delivery composition can be controlled and tailored as well.

Faour does not teach an asymmetric polymeric membrane or the claimed properties of the present compositions, inherently or otherwise.

Even if Faour's compositions had been the same as the compositions described in the present claims, there is no teaching or suggestion in Faour of administration to a high-fat use environment (e.g., comprising at least about 0.5 wt% of dietary fat) as required by the present claims.

It is respectfully submitted for the reasons given above that the invention as claimed in rejected claims 1-7 and 9-22 is not obvious over Faour, and reconsideration and withdrawal of the rejection is therefore respectfully requested.

(2). Claims 8 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour US 6,004,582 in view of FDA press release or Camden US 6,136,835. The FDA press release and Camden are cited as teaching written matter for inclusion on/in a

container or package containing a dosage form, as is required in the present rejected claims drawn to a therapeutic package.

As discussed above, Faour does not teach or suggest asymmetric polymeric coatings or the claimed properties of the compositions described in the present claims, including suitability for administration to a high-fat use environment. Additionally, the mere fact that the inclusion of written matter in pharmaceutical container packaging is old in the art does not make obvious the particular content of the written matter in the presently claimed therapeutic packages, i.e., "non-limited as to whether the dosage form can be taken with or without food".

It is respectfully submitted, therefore, that the therapeutic package as claimed in rejected claims 8 and 9-22 are not obvious over Faour US 6,004,582 in view of FDA press release or Camden US 6,136,835. Reconsideration and withdrawal of the rejection is respectfully requested.

Supplemental IDS

A Supplemental IDS is being filed herewith to bring to the Office's attention (a) the IPER for the PCT application corresponding to the present application, as well as (b) the Written Opinion and (c) Examination Report prepared by the Australian Patent Office for the Singapore Patent Office concerning the patent application in Singapore corresponding to the present application. Copies of these documents are enclosed herewith. The references cited in these documents (WO 1999/44591, US 5612059 and US 5698220) were disclosed to the Office in earlier-filed IDS'. The cited '059 patent is discussed above.